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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/031,878

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Gordhanbhai N. Patel

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05/04/2006

DUNLAP, CODDING & ROGERS P.C.

PO BOX 16370

OKLAHOMA CITY, OK 73113

EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/031,878

Applicant(s)

PATEL, GORDHANBHAI N.

Examiner

LaToya C. Younger

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1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 40-42 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 40-42 and 45-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on February 7, 2006. Claims 1-11, 40-42, 45-48 are pending.

#### *Withdrawal of Rejections from Previous Office Action*

- The anticipation rejection over Sumimoto et al is withdrawn in view of Applicants' amendment to recite the activator as a halide anion and monovalent cation.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5-7, 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Ignacio et al.

Ignacio et al teach sterilization monitoring devices. The device comprise a dye, a halogen source and a binder resin. The dye is a pH sensitive dye that, when exposed to sterilant, will produce a color change from yellow to blue, for example (see Example 2). The halogen source is a compound such as an alkali metal halide salt (potassium bromide, for example). See col. 3, lines 31-39. The halogen source of Ignacio et al is equivalent to Applicants' claimed activator. The binder resin is a

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polymer such as cellulosic materials. The binder may be dissolved in water or solvent (col. 3, lines 40-53, lines 59-63).

It is noted that Ignacio et al do not disclose that the sterilization-monitoring device monitors ethylene oxide sterilization. However, since the claims are directed to the device itself, Applicants' intended use is not sufficiently limiting to constitute a patentable distinction because the device claims are limited only by their structural components. Thus, Applicants' claims are anticipated because Ignacio et al teach a sterilization indicator having the same structural features as those claimed.

*Claim Rejections - 35 USC § 103*

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 8-11, 40-42, 45, 47, 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al in view of Sumimoto et al.

Ignacio et al disclose sterilization monitoring devices. The devices comprise a dye, a halogen source and a binder resin. The dye is a pH sensitive dye that, when exposed to sterilant, will produce a color change from yellow to blue, for example (see Example 2). The halogen source is a compound such as an alkali metal halide salt (potassium bromide, for example). See col. 3, lines 31-39. The halogen source of is similar to Applicants' claimed activator. The binder resin is a polymer such as cellulosic materials. The binder may be dissolved in water or solvent (col. 3, lines 40-53, lines 59-63).

Ignacio et al differ from the claimed invention in that, while the reference teaches sterilization monitoring devices, the reference is silent to ethylene oxide sterilization monitoring specifically.

Sumimoto et al teach an indicator device for ethylene oxide gas. The device comprises

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an indicator composition having a polymer, a coloring agent, and an activator. The polymer is preferably nitrocellulose. Other polymers, including vinyl chloride and vinyl acetate were also used (col. 2, lines 24-36; col. 3, lines 56-69). The coloring agent is preferably a blue coloring agent (col. 3, lines 6-21). The activator is a basic substance such as sodium carbonate having a monovalent cation and an anion (col. 2, lines 45-54). Example 1 teaches all of the components dissolved in a solvent (ethyl acetate). Sumimoto et al teach that when the composition is exposed to ethylene oxide gas, an observable color forms. With respect to the method of claims 40-45, Sumimoto et al teach that the indicator composition is prepared and applied to a packaging bag. The packaging bag having the indicator is exposed to sterilization gas mixture having ethylene oxide. After exposure, an observable color change from blue to green formed. See Example 1. '

Therefore, recognizing that an indicator device comprised of an indicator, polymer layer and activator, one of ordinary skill in the art would have expected that the device of Ignacio et al would have been suitable for monitoring ethylene oxide sterilization processes, similarly to the manner in which the device is disclosed as monitoring peracid sterilization processes.

5. Claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio in view of Kipke et al.

The disclosure of Ignacio et al is described above. Ignacio et al fail to teach the particular dyes recited in claim 4 of the instant invention.

Kipke et al teach indicators for sterilization. As pH sensitive dyes, the reference discloses the dyes taught by Ignacio et al (fluorescein, phenolphthalein) and those claimed by Applicants (bromothymol blue, bromocresol purple). Thus, Kipke et al provides for the equivalency between those dyes claimed and those taught by Ignacio et al. It would have been obvious to one of ordinary skill in the art to substitute the dyes of Ignacio et al for others (such as bromothymol blue and bromocresol purple)

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known to be pH sensitive dyes for sterilization monitoring. Such as modification would provide an indicator that allows sterilization to be monitored by observing color changes, alleviating the need for costly equipment and highly trained users.

*Response to Arguments*

6. Applicant's arguments filed February 7, 2006 have been fully considered but they are not persuasive. In response to the rejections given in the previous Office action, Applicants argued that neither reference taught or suggested "halide anion" and a monovalent cation. The Examiner disagrees. Ignacio teaches a sterilization monitoring device comprising a polymeric resin, a dye and a halogen source. The polymer resin may be a cellulosic material and the dye is an an indicator. The halogen source, equivalent to Applicants' claimed activator, is a compound such as potassium bromide (halide anion and monovalent cation). See col. 3, lines 40-53, 59-63. Therefore, Ignacio et al do teach the activator compounds recited in Applicants' claimed invention. The anticipation rejection is maintained.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

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date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Thursday 10:30 a.m. - 7:00 p.m. and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MONIQUE T. COLE  
PRIMARY EXAMINER